REMARKS

Reconsideration of the above-identified application in view of the remarks following is respectfully requested. Claims 1-33 are in this case. Claims 1-10, 12-27 and 29-33 have been allowed. Claims 1, 3, 5-7, 11, 22, 26, and 28-33 have been amended. Claims 2 and 4 have been cancelled. New claims 34-51 have been added.

Claims 1, 6, 26, 29, 31 and 33 have been amended to replace the term 'hydrophilic solvent' with the term 'amphiphilic solvent'. Claim 30 has been amended to describe ethyl lactate as an amphiphilic solvent instead of as a lower alkyl hydroxy acid ester. Support for these amendments is derived from the specification at page 8, lines 14-17, which describe the solvent ethyl lactate, as being miscible in both organic and inorganic solvents, since it is more hydrophobic than ethanol.

Claims 1 and 26 have been amended to recite a solvent comprising a lower alkyl hydroxy alkanoic acid ester or a lower alkyl ester of N-alkyl pyrrolidone, instead of a lower alkyl ester of hydroxyalkanoic acid or an N-alkyl pyrrolidone. Support for this amendment is derived from the specification at page 9, lines 6-8, which teaches these esters as the preferred solvents, with "lower alkyl" defined as C1-4.

Claim 2 has been amended to be dependent on claim 3.

Claim 5 has been amended to be dependent on claim 1, and to define the amphiphilic solvent as including N-methyl pyrrolidone, as supported by original claims 4 and 5.

Claim 7 has been amended to replace the term 'high hydrophilic/hydrophobic balance' by the term 'hydrophilic', and the term 'low HLB' by 'hydrophobic'. Support for this amendment is derived from the specification at page 9, lines 26-29, which teaches

that a surfactant with high HLB (hydrophilic/hydrophobic balance) is hydrophilic, while a surfactant with low HLB is hydrophobic. The further restriction of high HLB being at least 8, and low HLB of less than 5 have been removed from claim 7, and rewritten as new independent claims 34 and 35.

Claim 13 has been amended to add bovine heart phospholipid, as supported by the specification at page 11, line 27.

Claims 30 has been amended to be dependent on claim 26.

Claims 31 and 32 have been amended to insert the words 'ester of' before 'N-alkyl pyrrolidone', as supported by the specification at page 9, paragraph, which teaches a hydrophilic solvent selected from lower alkyl esters of N-alkyl pyrrolidone.

New claims 34-51 have been added as follows:

Claims 34 and 35 recite that the hydrophilic surfactant has an HLB (hydrophilic/lipophilic balance) of at least 8 (claim 34) or at least 5 (claim 35).

Claim 36 recites a hydrophobic surfactant comprising a sorbitan fatty acid ester, as supported by the specification at page 10, line 11.

Claims 37 and 38 recite hydrophobic surfactants comprising PEG-6 glyceryl monooleate and propylene glycol laurate respectively, both as supported by the specification at page 10, line 25.

Claim 39 teaches a hydrophilic solvent comprising polyoxyethylene-sorbitan-fatty acid ester, as supported by the specification at page 10, lines 27-28.

Claim 40 teaches a hydrophilic solvent comprising sucrose fatty acid, as supported by the specification at page 10, lines 10-11.

Claim 41 teaches a composition in which the phospholipid of claim 12 is lecithin, as supported by the specification at page 11, lines 23-26.

Claim 42 teaches an amphiphilic solvent selected from the group consisting of ethylene glycol, glycofurol and PEG 400, as supported by the specification at page 9, lines 17-18.

Claim 43 teaches a method of treatment of autoimmune disease or inflammatory disease, as supported by the specification at page 35, line 23-24.

Claim 44 teaches a method of treatment of organ or tissue transplant rejection, as supported by the specification at page 35, lines 22-23.

Claims 45 and 46 teach methods of treatment using topical and parenteral administration, respectively, as supported by the specification at page 34, line 11, and at page 35, line 1, respectively.

Claims 47-49 teach methods of treatment using a capsule, a tablet, and a powder, respectively, as supported by the specification at page 35, lines 5-6.

Claims 50 and 51 teach a method and composition for administering a cyclosporin compound, supported by claim 1.

Rejections over 35 USC 112, second paragraph

The Examiner has rejected claims 11 and 28 over 35 USC 112, second paragraph, as failing to point out and distinctly claim the subject matter which the applicant regards as his invention due to the use of the trademark/trade names Cremophor EL, Cremophor RH 40 and Cremophor RH 60 to identify/describe polyethyleneglycol-hydrogenated castor oils. Claims 11 and 28 have been amended to replace the trade names with the

chemical names polyoxyl 35 castor oil, polyoxyl 40 hydrogenated castor oil, and polyoxyl 60 hydrogenated castor oil, respectively.

In view of the above amendments and new claims, Applicant feels that claims 1, 3 and 5 – 51 are now in condition for Allowance. Prompt Notice of Allowance is respectfully requested.

Respectfully submitted,

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Encs:

Petition for extension of time fee
Petition for additional claims fee